MAR 2 0 2001

Summary of Safety and Effectiveness Information	ORTHOTEC, LLC.
Premarket Notification, Section 510(k)	DECEMBER 15, 2000

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

Trade Name: *Zenith Plate System*

Common Name(s): Anterior cervical spine system

Classification Name(s): Spinal intervertebral body fixation orthosis.

2. Establishment Name & Registration Number:

Name: ORTHOTEC, LLC.
Number: 2031734

3. Classification(s):

§ 888.3060 Spinal intervertebral body fixation orthosis. (a) Identification. A spinal intervertebral body fixation orthosis is a device intended to be implanted made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is used to apply force to a series of vertebrae to correct ``sway back,'' scoliosis (lateral curvature of the spine), or other conditions. (b) Classification. Class II.

Device Class: Class II for all requested indications
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Product Code(s): KWQ

4. Equivalent Predicate Device:

ORTHOTEC, LLC. believes that the ***Zenith Plate System - Anterior Cervical Spinal Instrumentation*** is substantially equivalent to the following device system marketed by Sofamor/Danek of Memphis TN.

K993855, *Atlantis Anterior Cervical Plate System, Sofamor/Danek.*

The *Sofamor/Danek* brand cervical plates are cleared for marketing. The comparison device represents a cervical spinal instrumentation system and accessories that uses plates, screws, and other corresponding components, all of which are intended to be used for the surgical treatment of cervical spinal instability or deformity. Equivalence can be seen in the design, material composition, surgical technique and intended use.

5. Device Description:

Indications for Use:
The *Zenith Plate System, Anterior Spinal Instrumentation* is intended for anterior interbody fixation of the cervical spine. The *Zenith Spinal Instrumentation* is suitable for use to provide temporary stabilization of the anterior spine while awaiting bony fusion (healing) in patients with

degenerative disk disease (neck or radicular pain of discogenic origin with degeneration of the disk confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), or pseudoarthrosis and/or failed previous fusion.

Warning: This device is not cleared for screw attachment to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Materials. Materials for components of the ***Zenith Plate System*** are implant grade materials of titanium. The materials comply with applicable standards shown below:

Titanium Alloy	ASTM F136-92	ISO 5832-3

The system components include:

Screws & Plates
Instruments
Sterilizer trays

Table for Zenith Plate System - Cervical Plates

Zenith Plate Reference number	Plate Length
FT20-PF22	22mm
FT20-PF24	24mm
FT20-PF26	26mm
FT20-PF28	28mm
FT20-PF30	30mm
FT20-PF33	33mm
FT20-PF36	36mm
FT20-PF38	38mm
FT20-PF40	40mm
FT20-PF42	42mm
FT20-PF44	44mm
FT20-PF46	46mm
FT20-PF48	48mm
FT20-PF51	51mm
FT20-PF54	54mm
FT20-PF57	57mm
FT20-PF60	60mm
FT20-PF63	63mm
FT20-PF66	66mm
FT20-PF70	70mm
FT20-PF75	75mm
FT20-PF78	78mm
FT20-PF81	81mm
FT20-PF84	84mm
FT20-PF87	87mm
FT20-PF90	90mm
FT20-PF94	94mm
FT20-PF98	98mm
FT20-PF102	102mm
FT20-PF106	106mm
FT20-PF110	110mm

Table for Zenith Plate System - Bone Screws

Length	Reference 4.0 mm	Reference 4.5 mm
10mm	FT10-4010	FT10-4510
11mm	FT10-4011	FT10-4511
12mm	FT10-4012	FT10-4512
13mm	FT10-4013	FT10-4513
14mm	FT10-4014	FT10-4514
15mm	FT10-4015	FT10-4515
16mm	FT10-4016	FT10-4516
17mm	FT10-4017	FT10-4517
18mm	FT10-4018	FT10-4518
19mm	FT10-4019	FT10-4519
20mm	FT10-4020	FT10-4520
21mm	FT10-4021	FT10-4521
22mm	FT10-4022	FT10-4522
23mm	FT10-4023	FT10-4523
24mm	FT10-4024	FT10-4524
25mm	FT10-4025	FT10-4525
26mm	FT10-4026	FT10-4526
27mm	FT10-4027	FT10-4527
28mm	FT10-4028	FT10-4528

Testing Summary. Fatigue testing of a typical system configuration was conducted on samples of titanium alloy. Samples were tested according to accepted engineering and scientific principals. Results indicated that the ***Zenith Plate System*** performs in an equivalent way.

6. *Applicant Name & Address:*

ORTHOTEC, LLC.
546 Hillgreen Drive
Beverly Hills, CA 90212
310.557.2000 ~ 310.843.9500 – fax

7. *Company Contact:*

Patrick Bertranou
ORTHOTEC, LLC.
546 Hillgreen Drive
Beverly Hills, CA 90212
310.557.2000 ~ 310.843.9500 - fax

8. *Submission Correspondent:*

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

9. *Performance Standards:*

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations.

10. *Special Controls:*

Special controls do not apply.

11. *Storage, Packaging & Sterilization Information:*

The *Zenith Plate System* - ***Anterior Cervical Spinal Instrumentation*** is supplied ***"NON-STERILE"*** and must be sterilized prior to use. The recommended sterilization process is high temperature steam autoclave sterilization. The recommended sterilization cycle will produce a Sterility Assurance Level (SAL) of at least 10^{-6}.

The validated cycle is:
Method: Steam
Cycle: Gravity
Temperature: 250°F (121°C)
Exposure Time: 30 minutes

All packages containing implants or instruments should be intact upon receipt. Damaged packaging may indicate the presence of unsafe product. If the package or product is damaged, the product should not be used and should be returned.

Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following cleaning, sterilization and accepted surgical sterile technique.

12. *Summary Comparison Table:*

FEATURE	*Zenith Plate System*	***Atlantis Anterior Cervical Plates.***	**SE?**
Indications for Use:	Temporary stabilization of the anterior spine while awaiting bony fusion (healing) in patients with degenerative disk disease (neck or radicular pain of discogenic origin with degeneration of the disk confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), or pseudoarthrosis and/or failed previous fusion.	SAME	YES
Design:	Anatomically curved metallic plate	SAME	YES
Sterile:	No - Must be Autoclaved	SAME	YES
Plate Sizes:	22mm - 110mm length in 2-4mm increments	EQUIVALENT	YES
Screw Sizes:	4mm & 4.5mm dia. 12-28mm length in 1 mm increments	EQUIVALENT	
Material:	Titanium and Titanium Alloy	SAME	YES
Origin:	France	USA	YES
Manufacturer:	OrthoTec, LLC	Sofamor/Danek	YES
Product Code:	KWQ	SAME	YES
K - Number:	K001535	K993855	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2001

Orthotic, L.L.C.
c/o Mr. David W. Schlerf
Buckman Company Incorporated
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523-3389

Re: K001535
Trade Name: Zenith Plate System, Anterior Cervical Spine Instrumentation
Regulatory Class: Class II
Product Code: KWP
Dated: December 15, 2000
Received: January 12, 2001

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K001535

Device Name(s): *Zenith - Plate System*
Anterior Cervical Spinal Instrumentation

Intended Use(s) of the Device:

The *Zenith Plate System, Anterior Spinal Instrumentation* is intended for anterior interbody fixation of the cervical spine. The *Zenith Spinal Instrumentation* is suitable for use to provide temporary stabilization of the anterior spine while awaiting bony fusion (healing) in patients with degenerative disk disease (neck or radicular pain of discogenic origin with degeneration of the disk confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), or pseudoarthrosis and/or failed previous fusion.

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K001535

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)